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I hereby certify that this paper is being facsimile transmitted (along with any documents identified below) to the U.S. Patent and Trademark Office on the date shown below.

Date: December 18, 2002 Signature: _____
Attorney

OFFICIAL

TO: EXAMINER RODNEY P. SWARTZ (Telephone No.: (703) 308-4244)
GROUP ART UNIT: 1617

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FROM: Perry E. Van Over
Reg. No. 42,197
Telephone No.: (202) 861-3917

DATE: December 18, 2002

RE: U.S. APPLICATION SERIAL NO.: 08/948,149
FILED: OCTOBER 9, 1997
ATTORNEY DOCKET NO.: 9491-033-27

TOTAL NUMBER OF PAGES INCLUDING THIS PAGE: 6

COMMENTS

In the event any fees are due, including any fees required under 37 CFR 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge the required fees to our Deposit Account No. 50-1442. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time.

The documents included with this filing by facsimile transmission are:

SUPPLEMENTAL AMENDMENT
DECLARATION UNDER 37 C.F.R. 1.132 (2 PAGES, EXECUTED)

DOCKET NO. 9491-033-27

#35
JM
12/19/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: BRIAN M. FENDLY, ET AL. ART UNIT: 1645
SERIAL NO.: 08/948,149 EXAMINER: SWARTZ, R.
FILING DATE: OCTOBER 9, 1997
FOR: ANTI-ERBB2 ANTIBODIES

SUPPLEMENTAL AMENDMENT

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

This Supplemental Amendment is submitted further to the Response filed November 18, 2002 (November 16, 2002 being a Saturday and November 17, 2002 being a Sunday) in answer to the Office Action dated July 16, 2002.

REMARKS

Applicants wish to thank the Examiner for the courtesy of permitting a personal interview with the Applicants' representative on December 10, 2002.

In accordance with the agreement of that interview, Applicants herewith are submitting an inventor's declaration under 37 C.F.R. §1.132, which is directed to the stringent restrictions placed on the experimental use of the claimed subject matter.

The antibodies, 7F3 and 7C2, were not publically distributed or publically available

more than one year prior to the October 18, 1996, the effective filing date of the patent application. The antibodies were not deposited nor were their sequences disclosed by any prior art references.

As indicated in the Rule 132 Declaration, any access to the material of the claimed invention was subject to the receiving party's prior agreement to a Genentech Material Transfer Agreement (MTA). The Rule 132 Declaration clearly establishes that Genentech maintained strict supervision and control over the invention throughout the course of the experimentation as required under the guidelines of MPEP §2133.03(e)(5-7) and relevant case law. Prior to receiving the materials, any party requesting materials under the restrictions of the Genentech MTA was required to submit the proposed research plan to Genentech for approval. The received materials could only be used for the Genentech approved research plan and could not be provided to any other party. Genentech's strict supervision of the research being conducted required that all results be submitted to Genentech for comment, recommendations, and approval. No oral or written disclosure of the receiving parties research was permitted without prior review and approval by Genentech. In sum, this is precisely the experimental use supervision and control required under MPEP §2133.03(e)(5-7) and case law recited therein.

CONCLUSION

In light of the above and the concurrently filed Rule 132 Declaration, Applicants believe that this application is now in condition for allowance and therefore request favorable consideration.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

PIPER RUDNICK LLP

Dec 18, 2002
Date

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Docket No. 9491-033-27

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: BRIAN M. FENDLY, ET AL. GAU: 1645
SERIAL NO: 08/948,149 EXAMINER: SWARTZ, R.
FILING DATE: OCTOBER 9, 1997
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DECLARATION UNDER 37 C.F.R. 1.132

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

I, Gail D. Phillips, do hereby declare and state that I am one of the inventors named in the above-identified application. I am a resident and citizen of the United States of America.

The antibodies 7F3 and 7C2 of the present invention are mentioned in Shepard et al., *J. Clin. Immuno.*, 11(3):117-127, 1992 (*See* Figure 2 on page 120) and in Lewis et al., Cancer Immunol. Immunother., 37:255-263, 1993 (*See* Table 2 and Figure 4) however, antibodies 7F3 and 7C2 were not deposited prior to October 17, 1996, the effective filing date of the application, and their sequences were not disclosed in the references in such a way that a skilled person could have reproduced those particular antibodies based on the references.

If an outside investigator had requested samples of the 7F3 or 7C2 antibodies prior to October 17, 1996, Genentech would only have provided the antibodies to the investigator if Genentech was able to approve a research plan proposed by the outside investigator. If the research plan was approved, Genentech would only have provided the research material to the outside investigator under a Material Transfer Agreement (MTA). The standard Genentech MTA at that time imposed strict restrictions or limitations on the use of the research material. In

particular, the laboratory receiving the research material under a Genentech MTA could only use the research material for a research plan, which had received the prior approval of Genentech and could not transfer the research material to others outside the laboratory receiving the research material. The MTA further required that the results of the research be submitted to Genentech for review, recommendations and comments prior to receiving Genentech's approval for the outside investigator to make any disclosure (orally or in writing) of the research results.

In sum, a third party requesting material from Genentech under an MTA would use the provided material only under a research plan approved by Genentech and the results of the third party's research would be subject to review by Genentech. Thus, the activity of any third party that acquired the material under the Genentech MTA would be under the supervision and control of Genentech. Genentech never relinquished non-experimental control of the material. Genentech had to give approval of the experiments prior to providing the material, prohibited the transfer of the material to others outside of the receiving laboratory, required the submission of all results of third party experiments to Genentech for recommendations and comments and thus controlled all experimental use of the materials.

All statements made herein of my own knowledge are true and all statements made on information and belief are believed true. Further, I am aware that willful false statements and the like are punishable by fine, imprisonment or both, 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the above-captioned patent application, and any patent to issue thereon.

DATE: 12/16/02

Gail D. Phillips

Gail D. Phillips